

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

ROCHESTER DRUG CO-OPERATIVE, INC.,
on behalf of itself and all others similarly
situated,

Plaintiff,

v.

ACTAVIS HOLDCO U.S., INC., FOUGERA
PHARMACEUTICALS, INC., PERRIGO
COMPANY PLC, PERRIGO NEW YORK,
INC., SANDOZ, INC., SUN
PHARMACEUTICAL INDUSTRIES LTD.,
TARO PHARMACEUTICAL INDUSTRIES,
LTD., and TARO PHARMACEUTICALS USA,
INC.

Defendants.

Civil Action No.

JURY TRIAL DEMANDED

DIRECT PURCHASER CLASS ACTION COMPLAINT

Plaintiff Rochester Drug Co-Operative, Inc. (“RDC” or “Plaintiff”) brings this class action, on behalf of itself and all others similarly situated against Defendants Actavis Holdco U.S., Inc. (“Actavis”) Fougera Pharmaceuticals Inc. (“Fougera”), Perrigo Company plc (“Perrigo Ireland”), Perrigo New York, Inc. (“Perrigo NY”),¹ Sandoz, Inc. (“Sandoz”), Sun Pharmaceutical Industries Ltd. (“Sun”), Taro Pharmaceutical Industries, Ltd. (“Taro Israel”), and Taro Pharmaceuticals USA, Inc. (“Taro USA”),² based upon personal knowledge as to facts pertaining to itself, and upon information and belief as to all other matters, and alleges as follows:

I. INTRODUCTION

1. This case concerns an anticompetitive conspiracy among Defendants to raise, fix, and maintain prices, allocate markets, and/or rig bids for generic desonide (“Desonide”).

2. Generic drugs – drugs that are equivalent to brand name drugs – have saved direct purchasers, consumers, and the American healthcare system tens of billions of dollars annually because they typically introduce competition into a market where none previously existed. Typically, when a first generic drug manufacturer enters a branded market, the generic drug is priced slightly lower than the branded drug. However, the appearance of a second generic drug manufacturer reduces the average generic price to nearly half the brand name price. As additional generic manufacturers enter the market, prices usually continue to fall. For branded products that attract a large number of generic manufacturers, the average generic price can fall to a small fraction of the branded price.

3. Over the last several years, however, that price dynamic has changed for a large

¹ Perrigo Ireland and Perrigo NY are together referred to as “Perrigo.”

² Taro Israel and Taro USA are together referred to as “Taro.”

number of generic drugs. Prices for dozens of generic drugs have skyrocketed for no apparent reason. These unusual price increases have sparked investigations by Congress, the United States Department of Justice Antitrust Division (“DOJ”), state attorneys general, and the media. These investigations have begun to reveal a reportedly broad, well-coordinated, and long-running series of schemes to fix prices, allocate markets, and rig bids for a number of generic drugs in the United States. These investigations have also revealed that Defendants’ collusion on generic drug prices was centered around trade associations, such as the Generic Pharmaceutical Association (“GPhA”), customer conferences, and other industry gatherings. As part of these ongoing investigations, the DOJ convened a grand jury in this District. This grand jury has issued subpoenas and other requests for information to various generic drug manufacturers on a variety of generic drugs. Recently, on December 12, 2016, the DOJ filed the first two criminal charges stemming from this investigation. *See United States of America v. Jeffrey A. Glazer*, No. 2:16-cr-00506-RBS (E.D. Pa.); *United States of America v. Jason T. Malek*, No. 2:16-cr-00508-RBS (E.D. Pa.). These cases are both pending in this District and allege that these former senior executives of generic drug maker Heritage Pharmaceuticals violated Section 1 of the Sherman Act by participating in conspiracies to fix prices, rig bids and allocate customers for generic Glyburide and Doxycycline.

4. According to a June 26, 2016 report by Policy and Regulatory Report (“PaRR Report”), the DOJ’s investigation is focusing on trade associations and is wide-ranging:

A PaRR source says prosecutors see the case much like its antitrust probe of the auto parts industry, which has gone on for years and morphed into the department’s largest criminal antitrust probe ever. Like in that case, prosecutors expect to “move from one drug to another in a similar cascading fashion.”³

³ Eric Palmer, *DOJ Criminal probe takes a look at trade associations*, FiercePharma

5. Desonide is a widely prescribed topical corticosteroid that health care providers use to treat a variety of skin conditions, such as eczema and dermatitis. Because Desonide is a lower strength topical drug, physicians often prescribe it for pediatric patients or for adult patients to use in sensitive areas, like the eyelids.

6. Defendants Actavis, Fougera, Perrigo, and Taro have been the primary manufacturers of Desonide available for purchase in the United States. Defendant Sandoz acquired Fougera in 2012.

7. Since at least 1994, manufacturers of generic drugs have had regulatory approval to market generic forms of Desonide. For much of that time, prices for generic forms of Desonide were low because generic manufacturers engaged in robust price competition, as typically occurs among generic drug manufacturers in the absence of collusion.

8. Prices for Desonide have not remained low, however. Beginning in July 2013, shortly after two meetings of generic pharmaceutical manufacturers attended by Defendants Fougera, Perrigo, Sandoz, and Taro, Defendants acted in concert to raise the price of Desonide in unison by a dramatic margin. Although Actavis did not enter the Desonide market until November 2013, it too joined the conspiracy and implemented price increases. These increases resulted from Defendants' horizontal price-fixing agreement.

9. During a single week in July 2013, Defendants Fougera, Perrigo, Sandoz, and Taro collectively raised prices for Desonide more than six-fold, with certain product offerings increasing in price by more than 800%. Whereas, at the beginning of 2013, a 60-gram tube of

(July 10, 2015), *available at* <http://www.fiercepharma.com/regulatory/doj-criminal-probe-takes-a-look-at-trade-associations>.

Desonide cream cost \$26.75, as of December 12, 2013, the cost was nearly \$225.

10. Defendants' prices have stabilized at artificially high levels. As of December 2016, Desonide prices remain nearly more than 500% above their pre-July 2013 levels.

11. A report issued in August 2016 by the United States Government Accountability Office ("GAO") found that Desonide topical cream 0.05% and Desonide topical ointment 0.05% both "experienced an extraordinary price increase" from 2013 to 2014.⁴

12. The price hikes have not been the result of competitive market forces. Instead the price hikes were the result of Defendants' conspiracy to fix, raise, maintain and stabilize the prices of, and/or allocate customers and markets and rig bids for, Desonide. The price increases were neither the product of a competitive market, nor made necessary by any increased manufacturing costs. And because generic pharmaceutical manufacturers do not need to incur the research and development costs that brand manufacturers invest to develop new prescription drugs, Defendants' price increases cannot be attributed to the need to fund research and development. Defendants' price increases resulted from their conspiracy to restrain trade.

13. *Inter alia*, Defendants realized their conspiracy through private and public communications and meetings such as trade association meetings held by the GPhA. Given the small number of competitors and the high barriers to entry in the market for Desonide the market was ripe for collusion. Defendants recognized this and engaged in anticompetitive actions that allowed them to sustain their unlawful supracompetitive pricing.

14. Defendants Taro, Fougera, Sandoz, Sun and Actavis have been subpoenaed by

⁴ GAO, Report to Congressional Requesters, Generic Drugs Under Medicare: Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases (Aug. 2016), available at <http://www.gao.gov/products/GAO-16-706>.

the DOJ's grand jury in this District as part of its ongoing investigation of anticompetitive practices in the generic pharmaceutical industry.

15. Defendants have collectively and unlawfully colluded to restrain and/or eliminate competition by engaging in an anticompetitive conspiracy designed to raise prices and foreclose competition in the market for Desonide in the United States, in violation of Section 1 of the Sherman Act. This misconduct enabled each and every Defendant to overcharge direct purchasers for the generic drugs.

16. As a result of Defendants' scheme to fix, raise, maintain, and stabilize the prices of Desonide, direct purchasers such as Plaintiff RDC, have paid and continue to pay supracompetitive prices.

17. Plaintiff RDC brings this civil antitrust action on behalf of a proposed class of direct purchasers of (1) Desonide topical cream 0.05% and (2) Desonide topical ointment 0.05% (collectively, "Desonide"). Plaintiff seeks overcharge damages arising out of Defendants' agreement not to compete in the market for Desonide.

II. JURISDICTION AND VENUE

18. This action arises under section 1 of the Sherman Act, 15 U.S.C. § 1 and section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover treble damages, costs of suit and reasonable attorneys' fees for the injuries sustained by RDC and members of the proposed Class (defined below) resulting from Defendants' conspiracy to restrain trade in the United States. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a), 1407, and 15 U.S.C. § 15.

19. Venue is proper in this District pursuant to 15 U.S.C. §§ 15(a), 22 and 28 U.S.C.

§§ 1391(b), (c), and (d) because during the Class Period (defined below), the Defendants resided, transacted business, were found, or had agents in this District, and a substantial portion of the alleged activity affected interstate trade and commerce discussed below has been carried out in this District.

20. During the Class Period, Defendants sold and shipped generic drugs in a continuous and uninterrupted flow of interstate commerce, which included sales of Desonide in the United States, including in this District. Defendants' conduct had direct, substantial, and reasonably foreseeable effects on interstate commerce in the United States, including in this District.

21. This Court has personal jurisdiction over each Defendant because, *inter alia*, each Defendant: (a) transacted business throughout the United States, including in this District; (b) participated in the selling and distribution of Desonide throughout the United States, including in this District; (c) had and maintained substantial contacts with the United States, including in this District; or (d) was engaged in an unlawful conspiracy to inflate the prices for Desonide that was directed at and had the intended effect of causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

III. PARTIES

A. Plaintiff

22. Plaintiff Rochester Drug Co-Operative, Inc. is a stock corporation duly formed and existing under the New York Cooperative Corporations Law, with its principal place of business at 50 Jet View Drive, Rochester, New York 14624. During the Class Period, as defined below, RDC purchased Desonide directly from one or more Defendants at supracompetitive

prices thereby suffering injury to its business and property.

B. Defendants

23. Defendant Actavis Holdco U.S., Inc. (“Actavis”) is a corporation with its principal place of business in Parsippany, New Jersey. In August 2016, Teva Pharmaceuticals U.S., Inc. (“Teva”) acquired Allergan plc’s (“Allergan”) generics business (including Actavis generics).⁵ Actavis manufactures, markets, and sells generic drug products. During the Class Period, Actavis sold Desonide in the United States.

24. Defendant Fougera Pharmaceuticals, Inc. (“Fougera”) is a New York corporation with its principal place of business in Melville, New York. Fougera markets and sells Desonide throughout the United States.

25. Defendant Sandoz, Inc. (“Sandoz”) is a Colorado corporation with its principal place of business in Princeton, New Jersey. Sandoz is the United States affiliate of Sandoz International GmbH, a company organized and existing under the laws of Germany, with its principal place of business in Holzkirchen, Germany. Sandoz is responsible for the distribution of drugs developed and manufactured by Sandoz International GmbH. Together Sandoz and Sandoz International GmbH operate as the generic pharmaceuticals division of Novartis International AG, a global healthcare company based in Switzerland. In 2012, Novartis acquired Fougera for approximately \$1.5 billion.

26. Defendant Perrigo New York, Inc. (“Perrigo NY”) is a Delaware corporation with its principal place of business in New York, New York. Perrigo NY markets and sells

⁵ In connection with this acquisition, Allergan assigned certain assets of its “generics business” to Actavis, so that by acquiring Actavis, Teva also acquired Allergan’s generics business.

Desonide through the United States.

27. Defendant Perrigo Company plc (“Perrigo Ireland”) is a company organized and existing under the laws of Ireland with its principal place of business in Dublin, Ireland.

Defendant Perrigo NY is a wholly-owned subsidiary of Defendant Perrigo Ireland.

28. Defendant Taro Pharmaceuticals USA, Inc. (“Taro USA”) is a New York corporation with its principal place of business in Hawthorne, New York. Taro USA markets and sells Desonide in the United States.

29. Taro Pharmaceutical Industries Ltd. (“Taro Israel”) is an Israeli company with its principal place of business in Haifa, Israel. Defendant Taro USA is a wholly-owned subsidiary of Defendant Taro Israel.

30. Defendant Sun Pharmaceutical Industries, Inc. (“Sun”) is an Indian corporation with its principal place of business located in Cranbury, New Jersey. In 2010, Sun acquired a controlling stake in Taro Israel.⁶

31. All of Defendants’ actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants’ various officers, agents, employees, or other representatives while actively engaged in the management of Defendants’ affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, or with the actual, apparent, or

⁶ Rumman Ahmed, *Sun Pharma Acquires Controlling Stake in Taro*, THE WALL STREET JOURNAL (Sept. 22, 2010), available at <http://www.wsj.com/articles/SB10001424052748704129204575507013304953260>. In May 2016, Sun’s U.S. subsidiary received a grand jury subpoena from the Department of Justice Antitrust Division related to generic products and pricing. See Siddharth Vikram Philip, *Sun Pharma Says U.S. Unit Gets Subpoena in Antitrust Probe*, BLOOMBERG (May 28, 2016), available at <http://www.bloomberg.com/news/articles/2016-05-28/sun-pharma-says-u-s-unit-subpoenaed-in-antitrust-investigation>.

ostensible authority of Defendants.

IV. UNIDENTIFIED CO-CONSPIRATORS

32. Other persons, firms, entities and corporations, not named as Defendants in this Complaint, have participated as co-conspirators with Defendants in the violations alleged herein, and have aided, abetted, and performed acts and made statements in furtherance of the conspiracy.

33. The true names and capacities of these unidentified co-conspirators, whether individual, corporate, associate, or representative, are unknown to Plaintiff at this time. Plaintiff may amend this Complaint, as necessary, to allege the true names and capacities of additional co-conspirators as their identities become known through discovery.

34. At all relevant times, other persons, firms, and corporations, referred to herein as “co-conspirators,” the identities of which are presently unknown, have willingly conspired with Defendants in their unlawful scheme as described herein.

35. The acts alleged herein that were done by each of the co-conspirators were fully authorized by each of those co-conspirators, or were ordered or committed by duly authorized officers, managers, agents, employees, or representatives of each co-conspirator while actively engaged in the management, direction, or control of its affairs.

V. FACTUAL ALLEGATIONS

A. Generic Drug Market Overview

36. Under the Federal Food, Drug, and Cosmetic Act (“FDCA”), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application (“NDA”). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning

the safety and effectiveness of the drug, as well as information on applicable patents. 21 U.S.C. § 355(a), (b).

37. The Hatch-Waxman Act, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs.⁷ The Hatch-Waxman Act allows a manufacturer seeking approval to sell a generic version of a brand drug to file an Abbreviated New Drug Application (“ANDA”). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer’s NDA, and must show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug. This establishes that the generic drug is pharmaceutically equivalent and bioequivalent (together, “therapeutically equivalent”) to the brand drug. The FDA assigns generic drugs that are therapeutically equivalent to and are of the same dosage strength and form as their brand counterpart an “AB” rating.

38. The purpose of this coding is to allow users to determine whether the FDA has evaluated a particular approved product as therapeutically equivalent to other pharmaceutically equivalent products and to provide information on the basis of the FDA’s evaluations. Thus, generic drugs that are AB rated to the brand share the same safety and efficacy characteristics and are the same dosage size and form.

39. Generic drugs typically provide consumers with a lower cost alternative to brand drugs while providing the same treatment. Specifically:

A generic drug is the same as a brand-name drug in dosage, safety, strength, quality,

⁷ See Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

the way it works, the way it is taken and the way it should be used. FDA requires generic drugs have the same high quality, strength, purity and stability as brand-name drugs.⁸

40. Drug products are considered to be therapeutic equivalents only if they are pharmaceutical equivalents and if they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.⁹

41. Generic versions of brand drugs are priced significantly below the brand versions. Generic versions are liberally and substantially substituted for their brand counterparts. In every state, pharmacists are permitted (and, in some states, required) to substitute a generic product for a brand product unless the doctor has indicated that the prescription for the brand product must be dispensed as written. States adopted substitution laws following the enactment of the Hatch-Waxman Act.

42. The FDA has recognized that typically “[g]eneric competition is associated with lower drug prices[.]”¹⁰ A Federal Trade Commission study reached the same conclusion finding that typically in a “mature generic market, generic prices are, on average, 85% lower than the pre-entry branded drug prices.”¹¹ Economic literature in the healthcare market further confirms that competition by generic products results in lower prices for consumers. In the period before

⁸ Food and Drug Administration, Generic Drugs: Questions and Answers, *available at* <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm>.

⁹ Food and Drug Administration, Orange Book Preface, 36th Edition, *available at* <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm>.

¹⁰ Food and Drug Administration, Generic Competition and Drug Prices, *available at* <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm>.

¹¹ Federal Trade Commission, Pay-For-Delay: How Drug Company Pay-Offs Cost Consumers Billions, at 8 (Jan. 2010), *available at* <https://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff>.

generic entry, a brand drug commands 100% of the market share for that drug and the brand manufacturer can set the price without the impact of normal competitive market forces. Once the first generic enters the market, however, a brand drug rapidly loses sales, on average losing 90% of its sales within a year.¹²

43. A mature generic market, such as the market for Desonide, has several generic competitors. Because each generic is readily substitutable for another generic of the same brand drug, the products typically behave like commodities, with pricing being the main differentiating feature and the basis for competition among manufacturers.¹³ Over time, generics' pricing nears the generic manufacturers' marginal costs.

44. Generic competition usually enables purchasers to (a) purchase generic versions of the brand drug at a substantially lower price than the brand drug, and/or (b) purchase the brand drug at a reduced price. Generic competition to a single blockbuster brand drug product can result in billions of dollars in savings to direct purchasers, consumers, insurers, local, state, and federal governments, and others. Indeed, one study found that the use of generic medicines saved the United States healthcare system \$254 billion in 2014 alone, and \$1.68 trillion between 2005 and 2014.¹⁴

¹² *Id.*

¹³ See, e.g., Federal Trade Commission, Authorized Generic Drugs: Short-Term Effects And Long-Term Impact, at 17 (Aug. 2011) (“[G]eneric drugs are commodity products marketed to wholesalers and drugstores primarily on the basis of price.”); Congressional Budget Office, “How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry” (July 1998).

¹⁴ Generic Pharmaceutical Association, Generic Drug Savings in the U.S., at 1 (2015), available at http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf.

B. Consolidation in the Generic Drugs Industry

45. Since 2005, consolidation has generally reduced the number of competitors in generic pharmaceutical markets.

46. Generic pharmaceutical industry leader Teva Pharmaceutical Industries Ltd., for example, acquired Ivax Corporation in 2006, Barr Laboratories in 2008, Ratiopharm—Germany’s second largest generic drug producer—in 2010; and Allergan’s generics business (including Actavis Generics) in 2016. Other major transactions that occurred during the same time period include Watson Pharmaceuticals’ acquisition of Andrx Corporation in 2006; Daiichi Sankyo’s purchase of a majority stake in Ranbaxy in 2008; Endo Pharmaceuticals’ 2010 acquisition of Qualitest; Perrigo’s acquisition of Paddock Laboratories, Inc. in 2011; and Sandoz’s acquisition of Fougere in 2012.

47. Consolidation reduces the number of potential competitors, rendering the market ripe for collusion.

48. The consequence of the generic drug industry’s consolidation and coordinated pricing activity has been higher prices for consumers. Market consolidation also has resulted in generic product lines being combined or discontinued, further reducing price competition.

49. Like the market for most generic drugs, the Desonide market is now highly concentrated. Defendants dominate the market for the generic forms of Desonide at issue here.

50. Thus, the Defendants’ concerted actions have had the ability to, and did, impact pricing and output of Desonide in the United States.

C. Desonide Price Increases

51. Desonide is a low-potency topical corticosteroid that first came to market in the

1970s. Desonide is used to treat swelling, itching, and redness caused by a variety of skin conditions. Because of its relatively low potency, Desonide is widely used to treat skin conditions in children and to treat sensitive areas and folds of the skin in adults.

52. In 2013, Defendants caused the price of Desonide to dramatically increase in unison. During a single week in July 2013, the price of Desonide increased by a magnitude of several hundred percent. These increases were the subject and product of a horizontal agreement among Defendants to increase pricing and restrain competition.

53. Each of the Defendants met twice in 2013 prior to implementing these price increases. Both meetings occurred at GPhA events.

54. The GPhA describes itself as “the nation’s leading trade association for manufacturers and distributors of generic prescription drugs, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic industry.” The GPhA was formed in 2000, after the merger of three other generic drug trade associations—the Generic Pharmaceutical Industry Association, the National Association of Pharmaceutical Manufacturers, and the National Pharmaceutical Alliance.

55. Defendants Perrigo Ireland and Sandoz sit on the GPhA’s board of directors.

56. Defendants Actavis, Perrigo Ireland, Sandoz, Sun and Taro Israel attended the GPhA’s Annual Meeting in Orlando, Florida on February 20, 21, and 22, 2013.

57. Defendants Actavis, Fougera, Perrigo Ireland, Sandoz, and Taro attended the GPhA’s CMC Workshop in North Bethesda, Maryland on June 4 and June 5, 2013.

58. Their meetings in February and June of 2013 provided Defendants with opportunities to collude.

59. Draft National Average Drug Acquisition Cost (“NADAC”)¹⁵ data demonstrates that shortly after the CMC Workshop in early June 2013, prices for Desonide experienced a dramatic, across-the-board increase in price.

60. The NADAC data shows that between July 2013 and January 2014, Defendants increased their prices for Desonide in tandem by more than 600%, with certain products increasing by nearly 900%.

61. Since Defendants were selling a commodity product, absent an agreement to fix prices, if any Defendant increased its price it would expect to lose sales to other manufacturers. Thus, it would not be in any Defendant’s unilateral self-interest to raise its price for Desonide unless it had agreed with its competitors that they would also raise their prices.

62. Defendants have acted in concert to maintain their artificially inflated prices for Desonide. As of December 2016, the cost of Desonide still remains nearly 500% higher than the cost prior to the June 2013 trade association meeting.

63. The below tables demonstrate the average NADAC price increases for each Desonide product at issue in this case. Table 1 shows the average price increases carried out by Fougera, Perrigo, Sandoz, and Taro at the product level during the week of July 11, 2013. Table 2 shows the average price increases from July 11, 2013 to December 21, 2016, demonstrating that Defendants’ pricing of Desonide has stabilized at supracompetitive levels. Although Actavis did not enter the Desonide market until November 2013, it too joined the conspiracy and

¹⁵ NADAC is a measure of the cost of drugs developed by the National Association of State Medicaid Directors to set a single national pricing benchmark based on average drug acquisition costs. The Draft NADAC price data is precise and accurate according to the Centers for Medicare and Medicaid Services.

charged the identical supracompetitive prices as the other Defendants.

Table 1
(Percent Increase Per-Unit Between July 11, 2013 and July 18, 2013)

Manufacturer	Amount	0.05% Cream	0.05% Ointment	Average
Taro	15g	441.74%	389.75%	415.75%
	60g	873.82%	847.69%	860.75%
Perrigo	15g	441.74%	389.75%	415.75%
	60g	873.82%	847.69%	860.75%
Fougera	15g	N/A	389.75%	389.75%
	60g	N/A	847.69%	847.69%
Average		657.78%	618.72%	631.74%

Table 2
(Percent Increase Per-Unit Between July 11, 2013 and December 21, 2016)

Manufacturer	Amount	0.05% Cream	0.05% Ointment	Average
Taro	15g	237.5%	331.81%	284.66%
	60g	545.45%	750.00%	647.72%
Perrigo	15g	237.5%	331.81%	284.66%
	60g	545.45%	750.00%	647.72%
Fougera	15g	N/A	331.81%	331.81%
	60g	N/A	750.00%	750.00%
Average		391.48%	540.90%	491.09%

64. Defendants' price increases were not necessitated by increased manufacturing costs. They were likewise not incurred to defray research and development costs. Instead, through their anticompetitive agreement to increase and maintain the price of Desonide, Defendants were able to substantially increase their revenues without having made investments in research, development, or other costs associated with bringing branded Desonide to market.

D. Pretextual Justifications

65. Defendants' price increases were not necessitated by increased manufacturing costs because Defendants realized record profits from Desonide sales during the relevant period.

66. The price increases were likewise not incurred to defray the cost to bring Desonide to market, which Defendants—manufacturers of generic, not branded Desonide—did not incur in connection with the at-issue products.

67. Accordingly, through their anticompetitive agreement to fix, increase, and maintain the price of Desonide, Defendants were able to substantially increase their revenues without having made investments in research, development, or other costs associated with bringing brand name Desonide to market.

E. Government Investigations

68. As noted above, Defendants' conduct in regards to generic drugs is under investigation by the DOJ, state attorneys general, Congress, and others.

69. On August 6, 2015, Allergan plc (which previously owned Actavis's generic operations prior to the Teva acquisition) filed a SEC Form 10-Q, in which it disclosed that "[o]n June 25, 2015, [Actavis] received a subpoena from DOJ's Antitrust Division seeking information relating to the marketing and pricing of certain of the Company's generic products and communications with competitors about such products."

70. On September 9, 2016, Defendant Taro Israel disclosed that on September 8, 2016, Defendant Taro USA, "as well as two senior officers in its commercial team, received grand jury subpoenas from the United States Department of Justice, Antitrust Division, seeking documents relating to corporate and employee records, generic pharmaceutical products and

pricing, communications with competitors and others regarding the sale of generic pharmaceutical products, and certain other related matters.”

71. Sandoz and Fourgera are also under DOJ investigation. According to a November 2016 Bloomberg report, “Novartis’s Sandoz unit [including Fougera] got a U.S. Justice Department subpoena in March [2016] requesting documents related to marketing and pricing of copycat medicines.”¹⁶

72. The fact that these companies and/or their employees received subpoenas from a federal grand jury is significant, as is reflected in Chapter 3 of the 2014 edition of the DOJ’s Antitrust Division Manual.¹⁷ Section F.1 of that chapter notes that “staff should consider carefully the likelihood that, if a grand jury investigation developed evidence confirming the alleged anticompetitive conduct, the Division would proceed with a criminal prosecution.” *Id.* at III-82. The staff request needs to be approved by the relevant field chief and is then sent to the Antitrust Criminal Enforcement Division. *Id.* “The DAAG [Deputy Assistant Attorney General] for Operations, the Criminal DAAG, and the Director of Criminal Enforcement will make a recommendation to the Assistant Attorney General. If approved by the Assistant Attorney General, letters of authority are issued for all attorneys who will participate in the grand jury investigation.” *Id.* at III-83. “The investigation should be conducted by a grand jury in a judicial district where venue lies for the offense, such as a district from or to which price-fixed sales were made or where conspiratorial communications occurred.” *Id.* Thus, the fact that the Defendants

¹⁶ Manuel Baigorri, *Novartis Said to Hold Talk to Buy Generics Maker Amneal*, Bloomberg (Nov. 13, 2016), available at <https://www.bloomberg.com/news/articles/2016-11-13/novartis-said-to-hold-talks-to-buy-u-s-generics-maker-amneal>.

¹⁷ Available at <http://www.justice.gov/atr/public/divisionmanual/chapter3.pdf>.

and certain of their employees received federal grand jury subpoenas is an indication that antitrust offenses have occurred.

73. That a target has applied for leniency is also significant. As the DOJ notes on its web site (<http://www.justice.gov/atr/frequently-asked-questions-regarding-antitrust-divisions-leniency-program>):

5. Does a leniency applicant have to admit to a criminal violation of the antitrust laws before receiving a conditional leniency letter?

Yes. The Division's leniency policies were established for corporations and individuals "reporting their illegal antitrust activity," and the policies protect leniency recipients from criminal conviction. Thus, the applicant must admit its participation in a criminal antitrust violation involving price fixing, bid rigging, capacity restriction, or allocation of markets, customers, or sales or production volumes before it will receive a conditional leniency letter. Applicants that have not engaged in criminal violations of the antitrust laws have no need to receive leniency protection from a criminal violation and will receive no benefit from the leniency program.

The DOJ further provides that the leniency applicant must also satisfy the following condition, among others, to avail itself of the government's leniency: "[t]he confession of wrongdoing is truly a corporate act, as opposed to isolated confessions of individual executives or officials." *Id.*

74. The DOJ is poised to issue criminal indictments against various companies and individuals growing out this investigation and, as indicated above, issued its first two on December 12, 2016. On December 14, 2016, Bloomberg reported that "[t]he Justice Department accused two executives of colluding with other generic pharmaceutical companies to fix prices, the first criminal charges stemming from a sweeping two-year investigation. Jeffrey Glazer, a former chief executive officer of Heritage Pharmaceuticals Inc., and Jason Malek, an ex-

president, were charged in Philadelphia on Wednesday, according to court filings.”¹⁸

75. Twenty states attorneys general also filed their first action (relating to the generic drugs Glyburide and Doxycycline) based on their investigation into generic drug pricing on December 15, 2016.¹⁹ They have indicated that more actions are likely to follow, specifically alleging that they “have uncovered a wide-ranging series of conspiracies implicating numerous different drugs and competitors, which will be acted upon at the appropriate time...” The states attorneys general describe these conspiracies as “schemes to fix and maintain prices, allocate markets and otherwise thwart competition” and explain that they are carried out by generic companies through their senior executives who “exploit their interactions at various and frequent industry trade shows, customer conferences and other similar events, to develop relationships and sow the seeds for their illegal agreements. The anticompetitive agreements are further refined and coordinated at regular ‘industry dinners’, ‘girls nights out’, lunches, parties, and numerous and frequent telephone calls, emails and text messages.”²⁰ Connecticut’s attorney general George C. Jepsen commented on the suit that:

We believe this is just the tip of the iceberg. I stress that our investigation is continuing, and it goes way beyond the two drugs in this lawsuit, and it involves many more companies than are in this lawsuit.²¹

¹⁸ Tom Schoenberg, *U.S. Generic Drug Probe Seen Expanding After Guilty Pleas*, Bloomberg (Dec. 14, 2016), available at <https://www.bloomberg.com/news/articles/2016-12-14/u-s-files-first-charges-in-generic-drug-price-fixing-probe>.

¹⁹ Complaint, *State of Connecticut v. Aurobindo Pharma USA*, 16-cv-2056-VLB (D. Conn. Dec. 15, 2016), ECF No. 1.

²⁰ *Id.* at ¶¶ 7-8.

²¹ Katie Thomas, *20 States Accuse Generic Drug Companies of Price Fixing*, The New York Times (Dec. 15, 2016), available at <http://www.nytimes.com/2016/12/15/business/generic-drug-price-lawsuit-teva-mylan.html>.

Mr. Jepsen further commented that in the generic drug industry in the United States there is “a culture of cronyism where, whether it’s over a game of golf or a dinner or drinks, there’s just systematic cooperation.”²²

76. The United States Congress has been probing generic drug pricing for at least the last few years. In October 2014, U.S. Senator Bernie Sanders and U.S. Congressman Elijah Cummings sent letters to several drug manufacturers concerning price increases, including Defendants Actavis, Mylan, and Teva. In November 2014, a Senate committee held a hearing entitled ‘Why Are Some Generic Drugs Skyrocketing In Price?’²³ Most recently, in December 2016, the United States Senate Special Committee on Aging issued a lengthy report on drug pricing noting that its investigation “uncovered disturbing practices in pharmaceutical drug pricing.”²⁴

F. Generic Drug Markets are Extraordinarily Susceptible to Collusion

77. In addition to the pricing allegations set forth above, several market and other relevant factors give rise to a reasonable inference that Defendants acted unlawfully and in concert to raise and fix Desonide prices far above competitive levels. The United States market for Desonide has been characterized by numerous factors that facilitated Defendants’ conspiracy, including: (1) market concentration among a limited number of participants; (2) high barriers to

²² *Id.*

²³ See, e.g., U.S. Congress Press Release, *Congressional Panel to Probe Generic Drug Price Hikes* (Nov. 11, 2014), available at <http://democrats.oversight.house.gov/news/press-releases/congressional-panel-to-probe-generic-drug-price-hikes>.

²⁴ United States Senate Special Committee on Aging, *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System* (Dec. 2016).

entry; (3) mutual interchangeability of Defendants' products; (4) inelasticity of demand; (5) the lack of reasonably available substitutes for the products involved; (6) the absence of a competitive group of sellers; and (7) ease of information sharing among Defendants.

- (1) High Degree of Industry Concentration: As discussed above, a small number of competitors control a significant market share for Desonide.
- (2) Barriers to Entry: Costs of manufacture, intellectual property, and expenses related to regulatory oversight are barriers to entry in the generic drug market. Barriers to entry increase the market's susceptibility to a coordinated effort to maintain supracompetitive prices.
- (3) Demand Inelasticity: Desonide is a necessary treatment for millions of patients.
- (4) Lack of Substitutes: Many patients are unable to substitute other medications for Desonide.
- (5) High Degree of Interchangeability: Defendants' Desonide products are interchangeable within each dosage form, as they contain the same chemical compounds made from the same raw materials. Thus, Desonide products are standardized across suppliers and are highly interchangeable from one Defendant to the next.
- (6) Absence of Competitive Sellers: Defendants have maintained supracompetitive pricing for Desonide throughout the Class Period. Thus, Defendants have oligopolistic market power in the Desonide market, which enables Defendants to increase prices without losing market share.
- (7) Opportunities for Contact and Communication Among Competitors: As discussed above, certain Defendants are members of trade association GPhA and/or common attendees to GPhA meetings which provides and promotes opportunities to communicate.

VI. CLASS ACTION ALLEGATIONS

78. Pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3), Plaintiff brings this action on behalf of a Class defined as follows:

All persons or entities that directly purchased Desonide from Defendants in the United States and its territories and possessions at

any time during the period June 4, 2013 until the anticompetitive effects of Defendants' conduct cease (the "Class Period").

Excluded from the Direct Purchaser Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all federal governmental entities.

79. Members of the Class are so numerous that joinder of all members is impracticable. Plaintiff believes the Class Members are numerous and widely dispersed throughout the United States. Further, the Class is readily identifiable from information and records maintained by Defendants.

80. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff's interests are not antagonistic to the claims of the other Class Members, and there are no material conflicts with any other member of the Class that would make class certification inappropriate. Plaintiff and all members of the Class were damaged by the same wrongful conduct of Defendants.

81. Plaintiff will fairly and adequately protect and represent the interests of the Class. The interests of the Plaintiff are coincident with, and not antagonistic to, those of the Class.

82. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action litigation, and who have particular experience with class action litigation involving alleged violations of antitrust law in the pharmaceutical industry.

83. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class Members because Defendants have acted on grounds generally applicable to the entire Class, thereby determining damages with respect to the Class as a whole is appropriate. Such generally applicable conduct is inherent in Defendants'

wrongful conduct.

84. The common legal and factual questions, which do not vary from Class Member to Class Member and which may be determined without reference to individual circumstances of any Class Member, include, but are not limited to, the following:

- (a) Whether Defendants and their co-conspirators engaged in a contract, combination, or conspiracy to eliminate competition and thereby artificially increase the prices of Desonide in the United States;
- (b) The duration and extent of the alleged contract, combination, or conspiracy;
- (c) Whether Defendants and their co-conspirators were participants in the contract, combination, or conspiracy alleged herein;
- (d) The effect of the contract, combination, or conspiracy on the prices of Desonide in the United States during the Class Period;
- (e) Whether Defendants' conduct caused supracompetitive prices for Desonide;
- (f) Whether, and to what extent, the conduct of Defendants and their co-conspirators caused injury to Plaintiff and other members of the Class; and
- (g) Whether the alleged contract, combination, or conspiracy violated Section 1 of the Sherman Act, 15 U.S.C. § 1.

85. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons or entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including

providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

86. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

VII. ANTITRUST INJURY

87. During the Class Period, Plaintiff and Class Members purchased Desonide directly from Defendants. As a result of the Defendants' anticompetitive conduct, Plaintiff and Class Members paid more for Desonide than they would have and thus suffered substantial damages. This is a cognizable antitrust injury and constitutes harm to competition under the federal antitrust laws.

88. Because Defendants' unlawful conduct has successfully eliminated competition in the market, Plaintiff and Class Members have sustained, and continue to sustain, significant losses in the form of artificially inflated prices paid to Defendants. The full amount of such damages will be calculated after discovery and upon proof at trial.

89. Defendants' misconduct reduced competition in the Desonide market, reduced choice for purchasers, and caused injury to purchasers.

90. Defendants' anticompetitive conduct is ongoing, and as a result Plaintiff and the Class continue to pay supracompetitive prices for Desonide.

VIII. CLAIM FOR RELIEF VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1

91. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

92. Defendants are per se liable under Section 1 of the Sherman Act, 15 U.S.C. § 1, for the injuries and damages caused by their contract, combination, and conspiracy in restraint of trade as alleged herein.

93. There is no legitimate, non-pretextual, procompetitive business justification for Defendants' conspiracy that outweighs its harmful effect. Even if there were some conceivable justification, the conspiracy is broader than necessary to achieve such a purpose.

94. As set forth above, in violation of Section 1 of the Sherman Antitrust Act, Defendants entered into agreements with one another on the pricing and allocation of the market for Desonide in the United States. This conspiracy was per se unlawful price-fixing, or alternatively, was an unlawful restraint of trade under the rule of reason.

95. Each Defendant has committed at least one overt act to further the conspiracy alleged in this Complaint.

96. The conspiracy had its intended effect, as Defendants benefited from their collusion and the elimination of competition, both of which artificially inflated the prices of Desonide, as described herein.

97. As a result of Defendants' unlawful conduct, Plaintiff and Class Members have been injured in their business and property in that they have paid more for Desonide than they otherwise would have paid in the absence of Defendants' unlawful conduct. The full amount of such damages is presently unknown but will be determined after discovery and upon proof at trial.

IX. PRAYER FOR RELIEF

WHEREFORE, Plaintiff and Class Members pray for relief as set forth below:

- A. Certification of the action as a class action pursuant to Federal Rule of Civil Procedure 23, and appointment of Plaintiff as Class Representative and its counsel of record as Class Counsel;
- B. That acts alleged herein be adjudged and decreed to be unlawful restraints of trade in violation of the Sherman Act, 15 U.S.C. § 1;
- C. A judgement against Defendants, jointly and severally, for the damages sustained by Plaintiff and the Class defined herein, and for any additional damages, penalties, and other monetary relief provided by applicable law, including treble damages;
- D. By awarding Plaintiff and Class Members pre-judgment and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate from and after the date of service of the Complaint in this action;
- E. The costs of this suit, including reasonable attorney fees; and
- F. Such other and further relief as the Court deems just and proper.

X. DEMAND FOR JURY TRIAL


Plaintiff, on behalf of itself and others similarly situated, hereby requests a jury trial, pursuant to Federal Rule of Civil Procedure 38, on any and all claims so triable.

Dated: December 27, 2016

Respectfully submitted,

NASTLAW LLC

By:


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